

**CUMMINGS SCHOOL OF VETERINARY MEDICINE
TUFTS UNIVERSITY
Department of Infectious Disease and Global Health**

INFORMED CONSENT TO PARTICIPATE IN RESEARCH

Risk of zoonotic disease in coastal New England communities

Principal Investigator: Sam R. Telford III Sc.D.

INTRODUCTION

You are being invited to take part in a research study designed to describe the frequency with which residents of New England coastal communities experience tick, mosquito, or rodent borne infections (“zoonotic” infections: those of animals that may cause disease in humans) as well as discover the risk factors that lead to such infection.

Taking part in this research study is totally your choice. You can decide to stop taking part in this research study at any time for any reason. If you stop being in this research study, it will not affect how you are treated at your health care provider or by Tufts University.

Please read all of the following information carefully. Ask Dr. Telford, or his representative, to explain any words, terms, or sections that are unclear to you. Ask any questions that you have about this research study. Do not sign this consent form unless you understand the information in it and have had your questions answered to your satisfaction.

If you decide to take part in this research study, you will be asked to sign this form. You will be given a copy of the signed form. You should keep your copy for your records. It has information, including important names and telephone numbers, to which you may wish to refer in the future.

New things might be learned during this study that you should know about. The investigators will tell you about new information that may affect your willingness to stay in this study.

If you are eligible to participate and agree to be in the study, Dr. Telford may still choose to stop your participation in this study if he thinks it is in your best medical interest, such as possibility of bleeding complications due to medications you are currently taking, or if it might be very difficult and painful to take a blood sample.

If you have question about your rights as a research study subject, call the Tufts Medical Center and Tufts University Health Sciences Institutional Review Board (IRB) at (617) 636-7512. The Institutional Review Board is a group of doctors, nurses, and non-medical people who review human research studies for safety and protection of people who take part in the studies. Federal law requires the Institutional Review Board to review and approve any research study involving humans. This must be done before the study can begin. The study is also reviewed on a regular basis while it is in progress.

This research study has been reviewed and approved by the IRB of Tufts Medical Center and Tufts University Health Sciences.

PURPOSE OF STUDY

Ticks, mosquitoes, and rodents are known to transmit many infectious agents in New England, including some that can cause disease in people (also known as “zoonotic disease”). Lyme disease is very well known, but we know very little about how frequently people get the following infections:

Borrelia miyamotoi disease (BMD)

Babesiosis

Granulocytic ehrlichiosis/anaplasmosis

Ehrlichiosis

Tularemia

Tick borne encephalitis (Powassan and deer tick virus)

Rickettsiosis including Rocky Mountain Spotted Fever, epidemic typhus, and Q fever

Eastern equine encephalitis

West Nile virus

Undifferentiated arboviral fevers (California serogroup viruses such as Jamestown Canyon and Lacrosse virus; Highlands J virus; Snowshoe Hare virus; Cache valley virus; Kemerovo group viruses)

Heartland virus, Bourbon virus

Hantavirus

Bartonellosis

Leptospirosis

Alpha gal syndrome (not an infection, but an allergic condition)

We wish to determine (1) how common these infections are; (2) what are the risk factors for getting infected; and (3) measure the effects of any personal protection or environmental control strategy that gets implemented.

This study will invite residents of coastal New England sites, such as Cape Cod, the North and South Shore, the Elizabeth Islands; Narragansett Bay islands; Martha’s Vineyard; Nantucket; and Tuckernuck. Other New England sites may be included at the request of a Board of Health.

This study is not funded by any specific source.

As many as 600 people may participate in this study.

No drugs or devices will be administered. Participation is limited to answering a questionnaire and providing a blood sample. Additional questionnaires may be requested from participants based on their test results.

PROCEDURES TO BE FOLLOWED

If you choose to participate, we will ask you to answer a questionnaire about your tick, mosquito, or small animal exposure; whether you use repellants; whether you know that you have experienced any of these infections in the past; and other questions that are designed to help us understand how people get infected.

With your consent, we would ask to take a small blood sample (two tablespoons) by using a hypodermic syringe or “vacutainer”. Your serum will be separated from the rest of the blood and will be tested for evidence of exposure to the infections listed above; or to indicators of tick, mosquito, or rodent exposure such as tick saliva or mouse fur. We will not test for any other infection or substance. The non-serum component of your blood will be destroyed immediately.

With your consent, your serum sample will be marked with a number code and stored in a secure freezer for future analysis, for example, if a new disease was identified we would know for sure that it had never previously been found in your community. Your serum will never be tested for anything that is not related to ticks, mosquitoes, or rodents that serve as reservoirs of zoonotic infectious agents. It is possible that your sample might be stored for as long as 10 years. If you do not wish your sample to be stored for future analysis, please let Dr. Telford or his representative know and a notation documenting this request will be made on this form. You may ask that your sample be destroyed at any time by writing to Dr. Telford, emailing, or calling him by telephone. If you withdraw from the study, you may request that your sample and all records including your questionnaire be destroyed; if you do not request this, your sample and records may be retained for the study.

Depending on the community, you may only be asked for one questionnaire and blood sample; a yearly questionnaire and blood sample for 5 years; or twice a year sampling (before and after summer) for 5 years. Each visit will be for the shortest time possible, to allow for your informed consent and questions; filling out the questionnaire; and taking the blood sample.

RISKS

When blood is drawn, you may experience minor local pain and temporary bruising. You may feel light headed or even faint during or after the blood drawing procedure, but this feeling will disappear within a few minutes. You should not participate if you have a clotting disorder such as hemophilia or are taking anticoagulants (blood thinners).

There is no known risk for women of childbearing potential or to your nursing child.

There is a small risk of sepsis (blood infection by your normal skin bacteria) because we need to puncture your skin and vein to obtain the blood sample.

Certain questions on our questionnaires may be considered distressful or sensitive, thus there is a small risk of psychological risk. We have a plan to address any concerns to address this risk, if required.

We do not believe that there is any other physical or psychological risk. We do not believe that there would be financial, employment, political, or other risks if there is a loss of confidentiality (information about you collected during this study).

BENEFITS

Our blood tests are for research purposes and should not be considered diagnostic for any condition. However, you will be informed of the results of these tests, and your health care provider may choose to take our results into consideration when caring for you. The main benefit of your participation is to help your community understand whether ticks, mosquitoes, and small animals may impact the public health; and whether we can measure any effect of a control measure undertaken by the community.

GENETIC TESTING

We are not doing any genetic testing.

ALTERNATIVES

Some of the tests that we do may be done through your health care provider if he/she determines that you have or have had a compatible illness.

WHOM TO CONTACT

Principal Investigator: Dr. Sam Telford, Professor, Tufts University. 508-887-4236 (office); 508-717-7774 (cell); email sam.telford@tufts.edu

RESEARCH RELATED INJURY

If you have any illness that you think is related to our blood sampling, please call us immediately and seek care from your health care provider. We regret that there we have no way to pay for your treatment if you get hurt or sick as part of this study.

COSTS

There are no costs to you for your participation.

PAYMENT

You will not be paid for your participation in this study.

PRIVACY AND CONFIDENTIALITY

If you agree to take part in this research study, your personal information will not be given to anyone unless we get your permission in writing. We will make every effort to keep your information private, but it cannot be totally guaranteed. Certain government agencies (National Institutes of Health's Office for Human Research Protections or the Institutional Review Board of Tufts Medical Center and Tufts University Health Sciences may check records that identify you. This might include the informed consent form you signed and the records of this study. Such a review might be required to make sure all rules and guidelines were followed.

PARTICIPANT'S STATEMENT

I have read this consent form and have discussed with Dr. Telford or his representative the procedures described above. I have been given the opportunity to ask questions, which have been answered to my satisfaction. I understand that any questions that I might have will be answered verbally or, if I prefer, with a written statement.

I understand that I will be informed of any new findings developed during the course of this research study that may affect my willingness to stay in this research study.

I understand that my participation is voluntary. I understand that I may refuse to participate in this study. I also understand that if, for any reason, I wish to discontinue participation in this study at any time, I will be free to do so, and this will have no effect on my future care or treatment by my health care provider.

I understand that in the event I become ill or am injured as a result of participating in this research study, I should see my health care provider at my own expense. I understand that no funds to provide financial compensation for research-related injury or illness are available.

If I have any questions concerning my rights as a research subject in this study, I may contact the Institutional Review Board at (617) 636-7512.

I have been fully informed of the above-described study with its risks and benefits, and I hereby consent to the procedures set forth above.

I understand that as a participant in this study my identity and data relating to this research study will be kept confidential, except as required by law.

Date

Participant's Signature

I have fully explained to _____ the nature and purpose of the above-described study and the risks that are involved in its performance. I have answered all questions to the best of my ability.

Date

Principal Investigator or Representative's Signature